(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF INFORMAL CONFERENCE COMMITTEE

Tuesday, July 13, 2010
Second Floor
Board Room #4

Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Richmond, Virginia 23233

CALL TO ORDER:	A meeting of an informal conference committee of the Board of Pharmacy was called to order at 3:15pm.
PRESIDING:	John O. Beckner, Committee Chairman
MEMBERS PRESENT:	David C. Kozera
STAFF PRESENT:	Elizabeth Scott Russell, Executive Director Caroline D. Juran, Deputy Executive Director Sammy Johnson, Assistant Director, Enforcement
Khurram Rashid, M.D. License # 0101-050539	Mr. Edward D. Rickert, Esq., Krieg DeVault, and Julie Geason, Vice-President of Pharmacy Services, InstyMeds, were present to discuss the application, received June 8, 2010, for approval of an innovative (pilot) program wherein Medics USA Primary and Urgent Care Centers ("MedicsUSA") would use an automated drug delivery system manufactured by InstyMeds Corporation to dispense acute care drugs to their own patients. Because the physician licensed to dispense would not visually inspect the drug prior to patient delivery, an allowance is necessary for waiving certain provisions of Board regulation 18VAC110-30-40.
Decision:	After consideration of the application and statements concerning the innovative (pilot) program, Mr. Beckner stated that the Committee approved the innovative (pilot) program for a period of one year from the date of inspection approving the first dispensing device under the auspices of a limited-use practitioner of the healing arts to sell controlled substances license, and it is contingent upon receiving additional information and upon other terms and conditions. Required additional information for submission includes: 1. An application for a limited-use practitioner of the healing arts to sell controlled substances license from each physician, to include Khurram Rashid, M.D., requesting the ability to dispense drug to his own patients and the designation of a physician at each location assuming the responsibility for the drug stock, the required inventories, the records of receipt and destruction, safeguards against diversion and compliance with the laws and regulations. Upon a change in the responsible licensee so designated at

each location, an inventory of all Schedule II through V controlled substances shall be conducted in the manner set forth in §54.1-3404 of the Drug Control Act of the Code of Virginia and such change shall immediately be reported to the board.

Other terms and conditions include:

1. A waiver, if necessary, of the requirement for 60 square feet in the designated controlled substances storage and selling area as required in Regulation 18VAC110-30-90;
2. Either the dispensing device shall be located in an area protected by a security system compliant with Regulation 18VAC110-30-120, i.e., consisting of motion detectors monitored by an outside entity that will notify appropriate law enforcement when breached with the code being restricted to dispensing physicians, or the dispensing device shall have a monitored alarm within the device with the alarm code restricted to the dispensing physicians and the device shall be located in an area protected by motion detectors that when breached shall notify appropriate law enforcement, with a waiver on the restriction regarding who may have access to the alarm code;
3. Access to the code or key for opening the device shall be restricted to times when a dispensing licensee is on-site and shall only be given to a registered pharmacy technician, or a nurse or physician assistant with training in compliance with Regulation 18VAC110-30-40;
4. Drugs delivered for loading into the device shall be placed in the device within a reasonable period of time, not to exceed 24 hours from delivery, to prevent possible diversion;
5. Each participating MedicsUSA shall be subject to one random, unannounced inspection by the Board or its designated representative within 12 months following the implementation of the innovative (pilot) program. This inspection is independent from any routine inspection. Khurram Rashid, M.D., on behalf of MedicsUSA, shall be solely responsible for the payment of an inspection fee of $150.00 each to be paid to the Board within thirty days from the date of the statement of monies owed that will be mailed following the inspection;
6. A visual inspection to verify accuracy of the final dispensed drug prior to delivery as performed in the process of verifying the accuracy of the dispensed drug in its entirety as required in Board regulation 18VAC110-30-40 will be waived, as well as certain provisions of Regulation 18VAC110-30-240 B and C, based on the presented information regarding the device's automation and bar-code

technology. Additionally, a sign shall be posted near the dispensing device informing patients that nonspecial packaging or non-safety closures are not available.

7. All prescription errors and the theft or loss of any drug in Schedules II-V shall be immediately reported to the Board and other authorities as necessary.
8. The dispensing physician is ultimately responsible for any counseling provided to the patient as required in Regulation 18VAC110-20-40.
9. The dispensing physicians shall comply with all other laws and regulations regarding the dispensing of controlled substances.
10. Any operational changes or modifications to the innovative (pilot) program shall be approved by the Board prior to initiation of the modification; and,
11. Reports of failure to comply with the terms and conditions of the waiver as set forth above shall constitute grounds for the rescission of the approval and an administrative proceeding shall be convened to determine whether the approval should be rescinded or modified.

ADJOURN: With all business concluded, the meeting adjourned at approximately 5:45pm.

Caroline D. Juran, Deputy Executive Director

John O. Beckner, Chairman

Date